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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,123

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Jose Ignacio Andres-Gil

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EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

05/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No. 10/524,123	Applicant(s) ANDRES-GIL ET AL.	
	Examiner Erich A. Leeser	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-10 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4,8 and 9 is/are allowed.
- 6) ☒ Claim(s) 5,7,10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-5, 7-10 and 13 are pending and under examination. Examiner acknowledges that Applicant amended claims 1-2 and cancelled claim 12. Applicant previously elected with traverse Group I compounds when Het is pyridinyl and the composition thereof. Applicant previously cancelled claims 6 and 11. Examiner previously rejected claims 1, 7, and 12 and objected to claims 2-5, 8-11 and 13.

Claim Rejections - 35 USC § 112

Examiner previously rejected claims 7 and 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not enable the instant compounds for use in methods to treat and/or “prophylaxis” depression, anxiety, movement disorders, psychosis, Parkinson’s disease and body weight disorders, with a therapeutically-effective amount of a compound of Formula (I) or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention in a manner commensurate with these claims.

Applicant argues that the “role of 5-HT in the treatment of depression and other disorders is exceedingly well documented, as detailed in [Cryan, J., et al., *5-HT_{1A} and Beyond: The Role of Serotonin and its Receptors in Depression and the Antidepressant Response*, Hum. Psychopharmacol. Clin. Exp. 15, 113-135 (2000)], and other references known to those of skill in the art” and “Applicants assert that sufficient experimental data has been provided to enable one of skill in the art to make and use the claimed invention.”

Examiner respectfully disagrees for the reasons of record. As such, Examiner maintains this rejection with regards to pending claim 7, and expands the rejection to include claims 10 and 13.

Examiner previously rejected claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Examiner finds Applicant's argument of record persuasive and as such withdraws this rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5, 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i). Claim 5 is indefinite by saying: "A compound" without defining particularly and distinctly what "compound(s)" is/are intended by name, structure or molecular formula. One skilled in the art would not know which compounds applicant regards as their invention .
- ii). The terminology *in vivo* in claim 5 is indefinite because it is unclear where the degradation takes place (e.g., cell tissue, etc.) to provide the compound of claim 1. Would a compound degraded in the blood be the same as a compound that degrades in the mouth or

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stomach? What is the structure, formula or name of the compound of the invention applicant regards as his invention prior to degradation to a compound of claim 1? The metes and bounds of the compound's identity prior to degradation cannot be determined. Clarification is required.

iii). Claims 10 and 13 are indefinite because the claim terms "antidepressants, anxiolytics, anti-psychotics and anti-Parkinson's disease drugs" are unclear. This rejection can be overcome by pointing out where in the specification Applicant sufficiently defines these terms so that one skilled in the art would be able to understand the metes and bounds of Applicant's invention. Clarification is required.

iv). Claim 13 is indefinite because the relative ratios of ingredients is unclear. How much of "a compound according to claim 1" is to be mixed with how much of "a compound selected from ..." is to be mixed with "a pharmaceutically acceptable carrier"?

Allowable Subject Matter

Claims 1-4 and 8-9 are patentable over Andres-Gil, et al., U.S. Patent No. 7,169,786 which contains the compound 3, 3a, 4, 5, 8, 9-hexahydro-3-[[4-[(2E)-3-phenyl-2-propenal]-1-piperazinyl]methyl]-furo[2',3':6,7]naphth[1,2-c]isoxazole. The difference between this compound and the instant compounds is that the instant compounds teach furanyl instead of tetrahydrofuranyl. Therefore, the claims are free of prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

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